Additional instructions for completing forms

MDT Form Guidance

Specific Fields

- *Has the patient been adequately staged based on conventional imaging to make the first major treatment decision?*
  - The first major treatment decision will be defined as:
    - Referral for surgical excision of either the primary tumour and/or a metastatic site
    - Instigation of definitive treatment using chemotherapy, radiotherapy or a combination of the two
    - Decision to offer palliative/supportive care only
    - Request for a highly invasive surgical staging procedure such as surgical mediastinal lymph node sampling (mediastinoscopy), video-assisted thoracoscopic surgery (VATS), or laparoscopy
- *Patient Stage Based on Conventional Imaging Performed ONLY*
  - See table below for definitions for T, N and M staging.

Definitions

Primary Tumor (T)

- TX Primary tumor cannot be assessed
- T0 No evidence of primary tumor
- Tis Carcinoma in situ: intraepithelial or invasion of lamina propria[1]
- T1 Tumor invades submucosa
- T2 Tumor invades muscularis propria
- T3 Tumor invades through the muscularis propria into pericolorectal tissues
- T4a Tumor penetrates to the surface of the visceral peritoneum[2]
- T4b Tumor directly invades or is adherent to other organs or structures[2,3]

Regional Lymph Nodes (N)[4]

- NX Regional lymph nodes cannot be assessed
- N0 No regional lymph node metastasis
- N1 Metastasis in 1–3 regional lymph nodes
- N1a Metastasis in one regional lymph node
- N1b Metastasis in 2–3 regional lymph nodes
- N1c Tumor deposit(s) in the subserosa, mesentery, or nonperitonealized pericolic or perirectal tissues without regional nodal metastasis
- N2 Metastasis in 4 or more regional lymph nodes
- N2a Metastasis in 4–6 regional lymph nodes
- N2b Metastasis in 7 or more regional lymph nodes

Distant Metastasis (M)

- M0 No distant metastasis
- M1 Distant metastasis
- M1a Metastasis confined to one organ or site (for example, liver, lung, ovary, nonregional node)
- M1b Metastases in more than one organ/site or the peritoneum

ANATOMIC STAGE/PROGNOSTIC GROUPS

Stage	T	N	M	Dukes*	MAC*
0	Tis	N0	M0	–	–
I	T1	N0	M0	A	A
	T2	N0	M0	A	B1
IIA	T3	N0	M0	B	B2
IIB	T4a	N0	M0	B	B2
IIC	T4b	N0	M0	B	B3
IIIA	T1–T2	N1/N1c	M0	C	C1
	T1	N2a	M0	C	C1
IIIB	T3–T4a	N1/N1c	M0	C	C2
	T2–T3	N2a	M0	C	C1/C2
	T1–T2	N2b	M0	C	C1
IIIC	T4a	N2a	M0	C	C2
	T3–T4a	N2b	M0	C	C2
	T4b	N1–N2	M0	C	C3
IVA	Any T	Any N	M1a	–	–
IVB	Any T	Any N	M1b	–	–

NOTE: cTNM is the clinical classification, pTNM is the pathologic classification. The y prefix is used for those cancers that are classified after neoadjuvant pretreatment (for example, ypTNM). Patients who have a complete pathologic response are ypT0N0cM0 that may be similar to Stage Group 0 or I. The r prefix is to be used for those cancers that have recurred after a disease-free interval (rTNM).
* Dukes B is a composite of better (T3 N0 M0) and worse (T4 N0 M0) prognostic groups, as is Dukes C (any T N1 M0 and Any T N2 M0). MAC is the modified Astler-Coller classification.

Notes

[1] Tis includes cancer cells confined within the glandular basement membrane (intraepithelial) or mucosal lamina propria (intramucosal) with no extension through the muscularis mucosae into the submucosa.

[2] Direct invasion in T4 includes invasion of other organs or other segments of the colorectum as a result of direct extension through the serosa, as confirmed on microscopic examination (for example, invasion of the sigmoid colon by a carcinoma of the cecum) or, for cancers in a retroperitoneal or subperitoneal location, direct invasion of other organs or structures by virtue of extension beyond the muscularis propria (that is, a tumor on the posterior wall of the descending colon invading the left kidney or lateral abdominal wall; or a mid or distal rectal cancer with invasion of prostate, seminal vesicles, cervix, or vagina).

[3] Tumor that is adherent to other organs or structures, grossly, is classified cT4b. However, if no tumor is present in the adhesion, microscopically, the classification should be pT1-4a depending on the anatomical depth of wall invasion. The V and L classifications should be used to identify the presence or absence of vascular or lymphatic invasion, whereas the PN site-specific factor should be used for perineural invasion.

[4] A satellite peritumoral nodule in the pericolorectal adipose tissue of a primary carcinoma without histologic evidence of residual lymph node in the nodule may represent discontinuous spread, venous invasion with extravascular spread (V1/2), or a totally replaced lymph node (N1/2). Replaced nodes should be counted separately as positive nodes in the N category, whereas discontinuous spread or venous invasion should be classified and counted in the Site-Specific Factor category Tumor Deposits (TD).

If you have any questions about how to complete this form please contact the Streamline C Trial Coordinator on:
020 7679 9688

Streamline C

Streamlining Staging of Colorectal Cancer with Whole Body MRI

CASE REPORT FORMS

6. MDT FORM

Patient Initials	☐☐☐
Trial Number	S T C – ☐☐☐

Please send ORIGINAL CRF forms to:

Streamline C Trial Coordinator
CR UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

General enquires: **020 7679 9891**

Telephone Registration: **020 7679 9880** *(between 9.00am and 5.00pm)*
Fax Registration: **020 7679 9871**

E-mail: **CTC.streamlineC@ucl.ac.uk**

Streamline C

Please keep a copy for source documents

Trial Number S T C – | | | | **Patient Initials** | | |

Site

FORM 6

MDT Form 1/4 COMPLETE LIVE IN MDT

Complete new form for every MDT in which the patient is discussed

Ensure to sign off every MDT form on pages 3/4 and 4/4

MDT Discussion

Date patient discussed at MDT *(dd/mm/yyyy)* | | | | | | | | |

Has patient been referred to liver MDT for first major treatment decision based on conventional imaging?

YES ☐ ***STOP*** *- Reveal WB-MRI in Liver MDT and complete Liver MDT - WB-MRI NOT REVEALED CRF*

NO ☐ *Continue*

Has patient been staged based on conventional imaging to make the first major treatment decision?

YES ☐ Signed _____ Print name _____ *Complete Column 1 of Table 2 and Continue*

NO ☐ ***STOP***

Final MDT diagnosis (or working diagnosis) primary colorectal cancer?

YES ☐ *Continue*

NO ☐ ***STOP*** *- Submit Change of Status CRF*

Patient Stage Based on Conventional Imaging Performed ONLY

T Stage (tick) T1 ☐ T2 ☐ T3 ☐ T4 ☐ Tx ☐

N Stage (tick) N0 ☐ N1 ☐ N2 ☐

M Stage (tick) M0 ☐ M1 ☐ Equiv ☐ *If M1 or equivocal complete 'Conventional Imaging Disease Site Form'*

REVEAL Whole Body MRI Images and report

DO NOT REVEAL WB-MRI BEFORE CONVENTIONAL IMAGING TREATMENT DECISION IS MADE

WB-MRI

Date WB-MRI performed *(dd/mm/yyyy)* | | | | | | | | |

Date WB-MRI revealed *(dd/mm/yyyy)* | | | | | | | | |

For Office use only

Date form received: _____ Date form entered: _____ Initials: _____

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Trial Number S T C – ☐☐☐

Patient Initials ☐☐☐

FORM 6

MDT Form 2/4 COMPLETE LIVE IN MDT

Based on the WB-MRI findings ALONE have the MDT requested (or would have requested) further investigations before first major treatment decision?

YES ☐ *Complete TABLE 1 and Continue*

NO (patient is NOT being referred to liver MDT) ☐ *Skip TABLE 1 and Continue*

NO (patient IS now being referred to liver MDT) ☐ *STOP - Reveal WB-MRI again in Liver MDT and complete Liver MDT CRF.*

TABLE 1 -Additional Staging tests required (or would have been required) based on WB-MRI alone

	Y/N	Reason for additional test *(eg. More information required, clarification of equivocal MRI finding)*	Performed as part of conventional staging? *Y/N* *(If yes do NOT complete remaining columns)*	Date Requested *DD/MM/YYYY*	Date Performed *DD/MM/YYYY*	N Stage *(if applicable)*	Metastatic disease reported? *Y/N/ equivocal*	If yes or equivocal state ALL sites *(e.g liver, lung, pleura) If equivocal add '(e)' eg "liver (e)"*
PET/CT								
MRI Liver								
Biopsy- State site _____								
Other- Please state _____								
Other- Please state _____								

Grey boxes may be filled in after the MDT

Based on the WB-MRI and any additional tests generated is the patient being referred to liver MDT for final treatment decision?

YES ☐ *STOP - Re-discuss WB-MRI in Liver MDT and complete Liver MDT- WB-MRI HAS BEEN REVEALED CRF*

NO ☐ *Continue*

Patient Stage based on WB-MRI (and any additional tests generated) ONLY

T Stage (tick) T1 ☐ T2 ☐ T3 ☐ T4 ☐ Tx ☐

N Stage (tick) N0 ☐ N1 ☐ N2 ☐

M Stage (tick) M0 ☐ M1 ☐ Equiv ☐ If M1 or equivocal complete *'WB-MRI and Additional Imaging Disease Sites Form'*

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Date form received: _____ Date form entered: _____ Initials: _____

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Trial Number S T C – ☐☐☐

Patient Initials ☐☐☐

FORM 6

MDT Form 3/4 COMPLETE LIVE IN MDT

TABLE 2- *Nature of MDT treatment decision after staging*

	Decision based on ONLY conventional imaging	Theoretical Decision based on ONLY WB-MRI (and any additional tests)	Decision based on ALL tests Final treatment decision
Date of MDT when decision made *(dd/mm/yyyy)*	d d / m m / y y y y	d d / m m / y y y y	d d / m m / y y y y
Metastatic status			M0 ☐ M1 ☐ Equiv ☐
	Please tick one treatment decision in this column	*Please tick one treatment decision in this column*	*Please tick one treatment decision in this column*
Surgical removal of primary alone	☐	☐	☐
Surgery for primary followed by planned adjuvant chemotherapy	☐	☐	☐
Surgery for primary followed by planned chemotherapy followed by surgical removal of metastasis	☐	☐	☐
Surgical removal of primary and metastatic site(s) alone	☐	☐	☐
Surgery for primary and metastatic site(s) followed by planned adjuvant chemotherapy	☐	☐	☐
Neo-adjuvant chemo (radio) therapy alone	☐	☐	☐
Neo-adjuvant chemo (radio) therapy alone followed by planned surgical removal of primary	☐	☐	☐
Neo-adjuvant chemo (radio) therapy alone followed by planned surgical removal of primary and metastatic site(s)	☐	☐	☐
Palliative care	☐	☐	☐
Other– Describe _____	☐	☐	☐

Is treatment decision based on WB-MRI (plus additional tests) different from that based on conventional imaging?

Yes ☐ **No** ☐ *If Yes, please state why- (e.g. additional metastatic disease, invasion into chest wall, unstable fracture)*

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

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Trial Number S T C – | | | |

Patient Initials | | |

Site |

FORM 6

MDT Form 4/4 CAN BE COMPLETED AFTER MDT

Equivocal Findings

Are you arranging future SHORT INTERVAL follow up imaging for equivocal findings over and above routine imaging follow up?

YES ☐ *Please detail below*

NO ☐ *Do NOT complete table 3 below*

TABLE 3 - Short Interval follow up imaging for equivocal findings

	Decision based on ONLY conventional imaging *State interval and reason (eg. 3 months, equivocal lung lesion)*	**Theoretical Decision based on ONLY WB-MRI (and any additional tests)** *State interval and reason (eg. 3 months, equivocal lung lesion)*	**Decision based on ALL tests Final treatment decision** *State interval and reason (eg. 3 months, equivocal lung lesion)*
CT Chest Abdomen and Pelvis			
CT Chest Alone			
PET/CT			
MRI liver			
Biopsy– Please state site _____ _____			
Other– Please state _____ _____			

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

Please return to: **Streamline C** Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For Office use only

Date form received: _____ Date form entered: _____ Initials: _____